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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,132	08/18/2003	Robert L. Sullivan	SMI0096.US	3311

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Todd T. Taylor
TAYLOR & AUST, P.C.
P.O. Box 560
142 S. Main St.
Avilla, IN 46710

EXAMINER

SHAFFER, RICHARD R

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,132

Applicant(s)

SULLIVAN ET AL.

Examiner

Richard R. Shaffer

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

The amended drawing filed on April 17th, 2006 is acknowledged and accepted by the examiner.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-12, and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiPietropolo (US Patent 4,751,922) in view of Tangram Technology Data File.

DiPietropolo discloses a flexible medullary reamer assembly comprising: a reamer (3) and attachment element both made of metal (**Column 4, Lines 39-41**); a solid or tubular (**Column 3, Lines 32-35** state a bore is optional) flexible shaft having a longitudinal axis and longitudinal length made of thermoplastics or composites (**Claims 2 and 6**), because DiPietropolo required torsional strength, the thermoplastics deemed appropriate would have included those that are rigid, further because the material would be rigid and flexibility required still to feed the shaft through an intramedullary canal, the area moment of inertia would have to be "relatively" low in order to allow for bending; a stainless steel (**Column 4, Lines 57-59**) chuck end (4); and the shaft and reamer to be fixed together (**Column 4, Lines 41-51**).

DiPietropolo discloses all of the claimed limitations except the use of Polyether ether ketone (PEEK) as well as range values for the "low" moment of inertia. Tangram Technology teaches (Introduction, Typical Applications, Physical and Mechanical Properties) that PEEK is a "new generation of engineering thermoplastics" that are

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suitable for use at high temperatures, have excellent chemical resistance, high strength, good resistance to burning, used in prosthetics and instruments, and has a low coefficient of friction and wear rate. DiPietropolo as discussed previously preferred thermoplastics and desired (**Column 3, Lines 29-32 and 55-59**) that the material possess the required degree of flexibility, torsional strength (high strength), resistance to abrasion (low wear rate), and repeatedly being steam sterilized (resistance to burning). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize PEEK as a thermoplastic in the device of DiPietropolo in order to meet the requirements of wear, torsional strength, heat resistance, and medical use.

In regard to the claimed range values for the “low” moment of inertia falling between 0.0003 inches³ to 0.000002 inches³ or 0.0002 inches³ to 0.00001 inches³, it would have been obvious to one having ordinary skill in the art at the time the invention was made to calculate ranges falling within those claimed by using inherent material properties of PEEK to design an intramedullary reaming shaft. It has been held that when the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed April 17th, 2006 have been fully considered but they are not persuasive. Applicant admits that DiPietropolo teaches a flexible medullary reamer and would consider thermoplastics in its design, but that PEEK would not be in that list. The reason given is that it is a well-known rigid material. The examiner would like to bring to applicant's attention that "flexible" and "rigid" are both relative terms. The device of DiPietropolo is clearly "rigid" to a point in order to maintain structural integrity in reaming a canal, but also is "flexible" in order to be fed into the canal. Tangram Technology teaches that PEEK is merely of greater strength and rigidity than many other thermoplastics. While it may be true that more than half of individuals may refer PEEK as being rigid rather than flexible, it does not mean it is not also flexible. Plus, as applicant clearly knows, the relativity of flexible or rigid depends partly on an object's ability to bend/flex without permanent damage to the structural integrity. A thin sheet or even a paper clip of metal is "flexible" while a large I-beam would not be in common usage. The difference is related to shape, which is related to the moment of inertia. As already explained, finding the optimum or workable ranges involves only routine skill in the art given a fixed set of parameters. The parameters in this case is the material properties of PEEK, in the shape of a shaft, and strong enough to withstand substantial torque. It has already been shown why PEEK would be a desirable material obviating any argument directed to the use of it in terms of the broad sense of intramedullary reamers.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
June 27th, 2006



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER